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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,151

09/18/2003

Sheng-Ping Zhong

03-151US1

8726

27774 7590 12/30/2008

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EXAMINER

RAE, CHARLESWORTH E

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

12/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/667,151</p>	<p><b>Applicant(s)</b> ZHONG ET AL.</p>	
	<p><b>Examiner</b> CHARLESWORTH RAE</p>	<p><b>Art Unit</b> 1611</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 01 December 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611

/C.R./ Examiner, Art Unit 1611

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Continuation of 11. does NOT place the application in condition for allowance because: applicant has failed to address the merits of the outstanding nonstatutory obviousness-type double patenting rejection even though this is not the only outstanding rejection remaining in the application (see applicant's Response, received 12/01/08, page 7). In addition, the instant claims are not found to be in condition for allowance.

Thus, this rejection is maintained for the reasons previously made of record in the Office action, mailed 06/09/08, pages 4-7.

With respect to the rejection under 103(a), it is noted that the instant claims are directed to an injectable formulation comprising a chemical ablation agent in an amount effective to cause necrosis and exemplifies a composition comprising NaCl 5-30 % by weight (specification, page 13, Example 3). The prior art also suggest injectable formulations comprising NaCl in amounts of 0 to 150 nM, as well as exemplifies formulations comprising NaCl ((US Patent 6,869,297, col. 4, lines 13-39, especially lines 33-37; col. 9, lines 30-55). In fact, 150 nM of NaCl as taught by the prior art is equal to 8.76 g NaCl, which overlaps with the instant chemical ablative amount of NaCl in the instant exemplified formulation comprising 5-30 % NaCl (= 5 - 30 grams NaCl). Hence, the prior art formulations comprising NaCl in amount of 150 nM (= 8.7 grams) would be capable of performing the instant claimed chemical ablative effect (i.e. an amount effective to cause tissue necrosis) since the prior art teaches an amount that is taught by applicant to be an "effective amount". Applicant's argument that the prior art fails to suggest or teach the instant claimed invention since it only teaches formulations to promote or accelerate soft tissue growth or regeneration is not found to be persuasive because applicant has not structurally distinguished the instant claimed subject matter from the prior art (see US Patent 6,869,297, col. 9, lines 37-53) nor as applicant provided any evidence to demonstrate that NaCl in amount of 150 nM as taught by the prior art is not capable of having an ablative effect (= cause tissue necrosis). Further, the prior art formulations comprising NaCl actually teaches KGF-2 for its wound promoting or accelerating healing effects and not NaCl (abstract; and col. 26, lines 31-57). Although the instant claimed formulations require the inclusion of an agent that has an ablative effect (e.g. Na Cl), the formulations do not preclude the inclusion of other actives ( e.g. KGF-2) that impart wound healing effects since independent claim 1, for example, recites the term "comprising" and there is no recited limitation requiring the formulation itself to have chemical ablative/tissue necrosis effects. Thus, the rejection under 103(a) is maintained for the reasons previously made of record in the Office action mailed (see Office action, mailed 06/09/08, pages 7-13).